Materialise N.V.
℅ Mieke Janssen
Quality Engineer
Technologielaan 15
Leuven, 3001
BELGIUM

June 5, 2019

Re: K190874
Trade/Device Name: Materialise Mimics Enlight
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 1, 2019
Received: April 11, 2019

Dear Mieke Janssen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190874

Device Name
Materialise Mimics Enlight

Indications for Use *(Describe)*

Materialise Mimics Enlight is intended for use as a software interface and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file.

It is also intended as a software to aid in reading and interpreting DICOM compliant images for structural heart and vascular treatment options. For this purpose, Materialise Mimics Enlight provides additional visualisation and measurement tools to enable the user to screen and plan the procedure.

The Materialise Mimics Enlight output file can be used for the fabrication of physical replicas of the output file using traditional additive manufacturing methods. The physical replica can be used for diagnostic purposes in the field of cardiovascular applications.

Materialise Mimics Enlight should be used in conjunction with other diagnostic tools and expert clinical judgement.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

K190874

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92

Company name	Materialise N.V.
Establishment registration number	3003998208
Street Address	Technologielaan 15
City	Leuven
Postal code	3001
Country	Belgium
Phone number	+32 16 744 571
Fax number	+32 16 39 66 06
Principal Contact person	Mieke Janssen
Contact title	Regulatory Affairs Manager
Contact e-mail address	Regulatory.Affairs@materialise.be
Additional contact person	Isabel Helena de Brito Manique
Contact title	Regulatory Affairs Consultant
Contact e-mail address	Regulatory.Affairs@materialise.be

Submission date

The date of the Traditional 510(k) submission is April 1, 2019.

Submission information

Trade Name	*Materialise Mimics Enlight*
Common Name	Image processing system
Classification Name	System, Image processing, Radiological
Classification product code	LLZ (892.2050)

Description and functioning of the device

Materialise Mimics Enlight for structural heart and vascular planning is a software interface that is organized in a workflow approach. High level, each workflow in the field of structural heart and vascular will follow the same kind of structure of 4 steps which will enable the user to plan the procedure:

1. Analyse anatomy
2. Plan device
3. Plan delivery
4. Output

To perform these steps the software provides different methods and tools to visualize and measure based on the medical images.

The user is a medical professional, like cardiologists, radiologists or clinical specialists. To start the workflow DICOM compliant medical images will need to be imported. The software will read the images and convert them into a project file. The user can now start the workflow and follow the steps visualized in the software. The base of the workflow is to create a 3D reconstruction of the anatomy based on the medical images to use this further together with the 2D medical images in the workflow to plan the procedure.

Indications for use

Materialise Mimics Enlight is intended for use as a software interface and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file.

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Materialise Mimics Enlight should be used in conjunction with other diagnostic tools and expert clinical judgement.

Predicate Devices

The *primary predicate device* to which substantial equivalence is claimed, which has been cleared for marketing in the United States, and which has not been subject to a design-related recall:

Trade or proprietary or model name	Mimics Medical
510(k) number	K183105
Decision date	March 27, 2019
Classification product code	LLZ (892.2050)
Manufacturer	Materialise N.V.

One of the *reference predicate devices* to which substantial equivalence is claimed, which has been cleared for marketing in the United States, and which has not been subject to a design-related recall:

Trade or proprietary or model name	3mensio Workstation
510(k) number	K153736
Decision date	May 27, 2016
Classification product code	LLZ (892.2050)
Manufacturer	Pie Medical Imaging B.V.

The other *reference predicate device* to which substantial equivalence is claimed, which has been cleared for marketing in the United States (under K173619) and which has not been subject to a design-related recall:

Trade or proprietary or model name	Mimics inPrint
510(k) number	K173619
Decision date	March 21, 2018
Classification product code	LLZ (892.2050)
Manufacturer	Materialise N.V.

Technological Characteristics

Comparison of technological characteristics with the **predicate device (Mimics, K183105) and the reference device (Mimics inPrint, K173619)**

The subject device Mimics Enlight employs similar fundamental technologies as Mimics and Mimics inPrint. Technological similarities include:

- Device functionality:
    - Imaging information: All devices import DICOM compliant imaging types.
    - Image segmentation: All devices share the same image segmentation functionalities.
    - Processing to output file: All devices generate an output file that can be used for the fabrication of physical replicas.
    - Measuring and planning: All devices have functionalities to perform measurements and pre-surgical planning.
- Device design: The subject device, like the reference device, originated from the same code base as the predicate device.

The following technological differences exist between the subject device and the predicate device:

- Device functionality:
    - Software organization: The subject device shares the technology and functionality of the predicate and reference device. However, for the subject device, functionality was organized as a guided workflow.

Comparison of technological characteristics with the one of the two **reference devices (3mensio, K153736):**

The subject device Mimics Enlight employs similar fundamental technologies as 3mensio. Technological similarities include:

- Device functionality:
    - Imaging information: The subject and reference device both import DICOM compliant imaging types.
    - Measuring and planning: The subject and predicate device both have functionalities to perform measurements and pre-surgical planning.
    - Software organization: The subject and reference device are both organized in a guide workflow.

The following technological differences exist between the subject device and the predicate device:

- Device functionality:
    - Image segmentation: While both devices allow to segment anatomy in the cardiovascular field, Mimics Enlight provides more controls to the user to review and fine-tune the segmentation.
    - Processing to output file: While both devices allow to export an output file, Mimics Enlight validated its output on a set of 3D printers to support the use of physical replicas for diagnostic purposes.
    - NeoLVOT measurement: While both devices include a manual NeoLVOT area measurement, the subject device also includes a semi-automated NeoLVOT area measurement.

Performance Data

Software verification and validation were performed, and documentation was provided following the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." This includes verification against defined requirements, and validation against user needs. Both end-user validation and bench testing were performed.

The geometric accuracy of virtual models created in the subject device Mimics Enlight was assessed via Bench testing. Accuracy of the virtual models was compared for the subject and predicate device. Deviations were within the acceptance criteria. This shows that for creating virtual models, Mimics Medical is substantially equivalent to the predicate device.

Apart from geometric accuracy of virtual models, also geometric accuracy of the physical replicas (produced by 3D printing virtual models) was assessed. This was conducted for cardiovascular models. The physical replicas were compared to the virtual models. Deviations were within the acceptance criteria, showing that virtual models can accurately be printed when using one of the compatible 3D printers.

Validation of the semi-automatic neo-LVOT (neo-Left Ventricular Outflow Tract) tool demonstrated a higher inter-rater consistency/repeatability.

In conclusion, all performance testing conducted demonstrated device performance and substantial equivalence to the predicate device.

Summary

The characteristics that determine the functionality and performance of the subject device Materialise Mimics Enlight are substantially equivalent to the device cleared under Mimics Medical (K183105), the primary predicate device, and also substantially equivalent to its reference predicate device 3mensio Workstation (K153736) and to its other reference predicate device Mimics inPrint (K173619). The non-clinical testing indicates that the subject device is as safe, as effective, and performant as the predicate device.